SEP 30 2011

Section 5 510(k) SUMMARY

SUMMARY OF SAFETY AND EFFECTIVENESS FOR BD NEXIVA™ DIFFUSICS™ CLOSED IV CATHETER SYSTEM

1. SUBMITTER INFORMATION:

Submitter:	Becton Dickinson Infusion Therapy Systems Inc 9450 South State Street Sandy, UT 84070
Contact Person:	Rachel LeBlanc Staff Regulatory Affairs Specialist
Telephone:	(801) 565-2649
FAX:	(801) 565-2749

Date Summary was prepared: September 20, 2011

2. DEVICE INFORMATION:

Trade Name:	BD Nexiva™ Diffusics™ Closed IV Catheter System
Common Name:	Peripheral Intravascular Catheter or IV Catheter
Classification:	80 FOZ - Intravascular Catheter
CFR Reference:	21 CFR 880.5200 – Class II
Classification Panel:	General Hospital

3. PREDICATE DEVICE INFORMATION:

Substantial equivalence is being claimed to the following legally marketed devices.

Trade Name:	BD Nexiva™ Closed IV Catheter System
Common Name:	Peripheral Intravascular Catheter or IV Catheter
Classification:	80 FOZ - Intravascular Catheter
CFR Reference:	21 CFR 880.5200 – Class II
Classification Panel:	General Hospital
Premarket Notification:	Special 510(k) K102520, Traditional 510(k) K032843

Trade Name:	BD Angiocath IV Catheter with Sideholes
Common Name:	Peripheral Intravascular Catheter or IV Catheter
Classification:	80FOZ – Intravascular Catheter
CFR Reference:	880.5200
Classification Panel:	General Hospital
Premarket Notifications:	K950301 (was a preamendment device before clearance under this 510(k) for a revised sterilization standard)

4. DESCRIPTION OF DEVICE:

The BD Nexiva Diffusics device is designed to minimize blood exposure. It includes a passive needle-shielding mechanism designed to reduce accidental needlestick injury. The closed system is designed to keep blood contained within the device throughout the insertion process, which may prevent potential exposure for clinicians and patients. The system consists of a radiopaque Vialon® material

catheter, a notched needle to enhance flashback visualization, a septum designed to remove visible blood from the needle surface that seals after needle removal, a stabilization platform, extension tubing, a clamp, a vent plug and a luer connector. The 18-24 gauge catheter systems are capable of withstanding high pressure injection procedures. The stabilization platform and luer adapter are color-coded. See Table 1 for a list of BD Nexiva Diffusics available catheter sizes.

Table 1. List of BD Nexiva™ Diffusics™ Available Catheter Sizes

Gauge Size	Color Code per ISO-10555-5	Length in inches
24 GA	Yellow	.75"
22 GA	Blue	1.0"
20 GA	Pink	1.0"
20 GA	Pink	1.25"
18 GA	Green	1.25"

5. INDICATIONS FOR USE

The BD Nexiva Diffusics intravascular catheter is inserted into a patient's vascular system to sample blood, monitor blood pressure or administer fluids. The BD Nexiva Diffusics catheters are suitable for use with power injectors when a direct connection is made.

6. DESCRIPTION OF SAFETY AND SUBSTANTIAL EQUIVALENCE

Technological Characteristics
Technological similarities between the subject BD Nexiva Diffusics Closed IV Catheter System and the predicate devices remain substantially equivalent. There are no new questions raised regarding safety or efficacy of the subject BD Nexiva Diffusics Closed IV Catheters.

Table 2. Comparison between BD Nexiva™ Diffusics™ and predicates

Factor/Component	BD Nexiva Diffusics	BD Nexiva (K102520)	BD Angiocath with Sideholes (K950301)
Same intended use	Yes	Yes	Yes
Same Vialon catheter material	Yes	Yes	No (Teflon)
Radiopaque catheter	Yes	Yes	Yes
Flashback visualization	Yes	Yes	No
Needle-shielding feature	Yes	Yes	No
Closed IV catheter system	Yes	Yes	No
Ethylene oxide sterilization	Yes	Yes	Yes
Single use, sterile device	Yes	Yes	Yes
Multiple gauge sizes and needle lengths	Yes	Yes	Yes

The BD Nexiva Diffusics (subject) has the same intended use and similar technological characteristics as the predicates.

7. **Bench Testing:**

Studies were designed and performed to demonstrate that the BD Nexiva Diffusics device met predetermined product specifications. Bench testing was performed to ensure the safety and effectiveness of the device, to verify conformity to the standards listed in this application, and to demonstrate substantial equivalence to the predicate. No new issues of safety and effectiveness were raised with the testing performed so therefore the BD Nexiva Diffusics (subject) is substantially equivalent to the predicate devices. Performance testing included in-vitro testing in accordance with ISO 10555-1 and ISO 10555-5 and included flow rate testing, catheter strength and performance, clamp performance, labeling durability, extension tube and septum integrity and biocompatiblity evaluation in accordance with ISO 10993-1.

8. **Clinical Tests Submitted:**

No clinical test results were included in this submission.

9. **Conclusions**

Performance testing was conducted in accordance with consensus standards and design control requirements. Nonclinical test results and technological characteristics of like gauge size catheters were shown to be equivalent between the subject device and the predicate device. The differences among the devices do not raise any issues of safety or effectiveness. The subject BD Nexiva Diffusics device met the minimum requirements and are substantially equivalent in design, materials, sterilization, principles of operations and indications for use to the predicates.

Based on the above summary and the enclosed sections of this premarket notification regarding substantial equivalence to the predicate device, Becton Dickinson Infusion Therapy Systems Inc. concludes that the BD Nexiva Diffusics device is substantially equivalent to the predicates and does not raise any new questions regarding safety and efficicacy.

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21CFR 807, subpart E under which a device can be marketed without premarket approval or reclasslication. A determination of substantial equivalency udner this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Rachel LeBlanc
Staff Regulatory Affairs Specialist
Becton Dickinson and Company (BD)
9450 South State Street
Sandy, Utah 84070

SEP 30 2011

Re: K111366
Trade/Device Name: BD Nexiva™ Diffusics™ Closed IV Catheter System
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: September 21, 2011
Received: September 22, 2011

Dear Ms. LeBlanc:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111366

Indications for Use

510(k) Number (if known)

Device Proprietary Name: BD Nexiva™ Diffusics™ Closed IV Catheter System

Indications for Use:

The BD Nexiva™ Diffusics™ intravascular catheter is inserted into a patient's vascular system to sample blood, monitor blood pressure or administer fluids. The BD Nexiva Diffusics catheters are suitable for use with power injectors when a direct connection is made.

Prescription Use ____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman 9/30/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111366